The COVID-19 Treatment Guidelines Panel's Statement on Bamlanivimab Plus Etesevimab for the Treatment of Mild to Moderate COVID-19 in Nonhospitalized Patients

Last Updated: September 15, 2021

On June 25, 2021, the distribution of bamlanivimab plus etesevimab was paused in the United States because of the increase in the combined frequencies of two SARS-CoV-2 variants of concern (VOC) circulating across the country: Gamma (P.1) and Beta (B.1.351). In recent months, the Delta (B.1617.2, non-AY.1/AY.2) variant has become the predominant variant circulating in all states. Because the combination of bamlanivimab plus etesevimab retains activity against the Delta variant, as of September 2, 2021, the use and distribution of these anti-SARS-CoV-2 monoclonal antibodies (mAbs) have been resumed in all U.S. states, territories, and jurisdictions.

With the availability of bamlanivimab plus etesevimab, the COVID-19 Treatment Guidelines Panel (the Panel) has updated its recommendations.

The Panel recommends using one of the following anti-SARS-CoV-2 mAb regimens (listed alphabetically and **not** in order of preference) to treat nonhospitalized patients with mild to moderate COVID-19 who are at high risk of clinical progression (see Anti-SARS-CoV-2 Monoclonal Antibodies for rating of the recommendations based on the risk of progression to COVID-19):

- **Bamlanivimab 700 mg plus etesevimab 1,400 mg** intravenous (IV) infusion in regions where the combined frequency of potentially resistant variants is low (see the Emergency Use Authorization fact sheet).
- **Casirivimab 600 mg plus imdevimab 600 mg** IV infusion or subcutaneous injection; *or*
- **Sotrovimab 500 mg** IV infusion

The bamlanivimab plus etesevimab combination has been shown to have a clinical benefit in people with mild to moderate COVID-19 who are at high risk for progression to severe disease and/or hospitalization.[1] The Delta variant, which has the L452R and T478K mutations, has demonstrated susceptibility to bamlanivimab plus etesevimab in laboratory studies.[2] Because the Delta variant is the predominant variant circulating throughout the United States, the Panel considers bamlanivimab plus etesevimab to be one of the recommended treatment options for this patient population. In laboratory studies, the Delta variant is also susceptible to casirivimab plus imdevimab and to sotrovimab, so these products continue to also be recommended for this patient population.

Because the proportions of circulating VOC evolve rapidly, the use and distribution of bamlanivimab plus etesevimab, or other anti-SARS-CoV-2 mAbs, may be restricted in areas with elevated frequencies of VOC that have markedly reduced in vitro susceptibility to a given regimen (e.g., the Gamma and Beta variants to bamlanivimab plus etesevimab).[3] Clinicians should visit the Department of Health and Human Services Public Health Emergency website for updates on the distribution of bamlanivimab plus etesevimab.

References

1. Dougan M, Nirula A, Azizad M, et al. Bamlanivimab plus etesevimab in mild or moderate COVID-19. *N Engl J Med*. 2021;Published online ahead of print. Available at: https://www.ncbi.nlm.nih.gov/pubmed/34260849.
2. Food and Drug Administration. Fact sheet for healthcare providers: emergency use authorization (EUA) of bamlanivimab and etesevimab. 2021. Available at: https://www.fda.gov/media/145802/download.
3. Food and Drug Administration. Bamlanivimab and etesevimab authorized states, territories, and U.S. jurisdictions. 2021. Available at: https://www.fda.gov/media/151719/download.